

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Investigating the effects of intravenous laser on creatinine and GFR in chronic kidney patients

Protocol summary

Study aim

Investigating the effects of intravenous laser on the recovery of patients with chronic kidney disease is based on the creatinine and GFR

Design

Double-blind clinical trial, patients are divided into two control and treatment groups in a simple randomization. The rand function of Excel software was used for randomization.

Settings and conduct

The study will be conducted in Shahada Tajrish Hospital in a double-blind manner. Patients and treating nephrologists are unaware of the type of treatment.

Participants/Inclusion and exclusion criteria

Patients with chronic kidney disease and consent is required to participate in the study and complete the treatment and follow-up process. Patients with pre-renal and post-renal acute kidney disease, patients with glomerulonephritis and patients who need immunosuppressive drugs, including lupus, patients who have taken omega-3 and corticosteroids in the last month, pregnant patients, sensitive to light and suffering from Malignancy is excluded from the study process.

Intervention groups

In the intervention group, intravenous laser works by using infrared rays from continuous or pulse infrared ((600-1100 nm) with an output power of 1-500 milliwatts). In this method, laser light is directly irradiated into the blood through a sterile disposable catheter. Two millimeters of optical fiber enters the vein and spreads into the blood circulation. This method is just like serum injection. In this study, it is for 7 sessions one day in between with a power of 2 milliwatts for 30 minutes. The control group is the same as the intervention group, but with the laser turned off

Main outcome variables

BUN, Cr, GFR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N44**

Registration date: **2023-06-20, 1402/03/30**

Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of intravenous laser on creatinine and GFR in chronic kidney patients

Public title

Investigating the effects of intravenous laser on creatinine and GFR in chronic kidney patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a chronic kidney disease called CKD and with GFR below 20 who have not been treated with dialysis.

Exclusion criteria:

Patients with pre-renal and post-renal acute kidney disease, patients with glomerulonephritis and patients who need immunosuppressive drugs, including lupus, patients who have taken omega-3 and corticosteroids in the last month, pregnant patients, sensitive to light and suffering from malignancy

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

All patients are divided into case and control groups based on the table of random numbers with a ratio of 1:1. The assigned group is placed in dark envelopes one after the other. This envelope will be opened by the treating doctor only after the initial evaluation of each person, and neither the patient nor the clinical evaluator will know about his treatment group. Etiology factors include sepsis, rhabdomyolysis and drugs in both match groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the control group, the Sham laser is used by the operator And the reashercher and the patient are unaware of the type of group

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in research of laser application in medical sciences research center

Street address

Shohadaye Tajrish hospital, shahdari street, Tajrish distinct

City

Tehran

Province

Tehran

Postal code

1989934370

Approval date

2023-03-01, 1401/12/10

Ethics committee reference number

IR.SBMU.LASER.REC.1401.009

Health conditions studied

1

Description of health condition studied

chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

serum Cr

Timepoint

before and after treatment

Method of measurement

blood samples

2

Description

24 hours GFR

Timepoint

before and after treatment

Method of measurement

24 hours urine analysis

3

Description

urine output

Timepoint

before and after treatment

Method of measurement

urine analysis

4

Description

Blood urea nitrogen

Timepoint

before and after treatment

Method of measurement

blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: continuous or pulsed intravenous or near-infrared laser (600-1100 nm) with a power of 2 MW for 30 minutes, which is irradiated into the blood through a sterile disposable catheter. Two millimeters of optical fiber are inserted into the vein and distributed in the blood circulation. Intravenous laser is performed every other day for 7 sessions.

Category

Treatment - Devices

2

Description

Control group: Sham laser

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish hospital

Full name of responsible person

Esmat Ghanei

Street address

Shohadaye-Tajrish Hospital, Shahr-dari st, Tajrish Sq, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Yaman st, Danshjo Blvd, Velenjak st

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammadreza Razzaghi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Esmat Ghanei

Position

associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The publication is in the form of an article and it is not necessary to provide data in the article

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available